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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,981	03/03/2000	Julie A. Bearcroft	P01952US0	5566

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/517,981

Applicant(s)

BEARCROFT ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 20-22, 26, 64, 65 and 67-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 20-22, 26, 64, 65 and 67-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4,9,20,21,26,64,67,69,70,75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al. (5676700). Fig. 1 shows a shaped particle **10** having a center portion **C** and at least four tapered extremities **12** projecting from the center portion. It can also be seen in Fig. 1 that the ends of the extremities show a circular cross-sectional configuration. Additionally, as seen in Figs. 1 and 2, the extremities are of the same shape, size and the angles between adjacent extremities in the particle are approximately equal. Black also discloses the particle is made of materials such as ceramic or bioactive glass, col. 4, lines 14-18. Black additionally discloses the shaped particle is used for repair of bone, i.e. in diseased bone, voids in bone, col. 1, lines 30-60. Fig. 4 illustrates an array of shaped particles.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 6,10-13, 22,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Chen et al. (6180606). Black is explained supra. However, Black does not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair are formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can

Art Unit: 3738

be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute different ceramics and use calcium phosphate or combinations of materials such as polymer composites as taught by Chen for the particles of Black in order to enhance the osteogenic potential of the composition being used.

Claims 5-8, 71, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Barralet (Biomaterials, 1993). Black is explained supra. However, Black does not disclose the ceramic as gypsum or the array to have a porosity between 40-80%. Barralet teaches that calcium sulfate or gypsum having a porosity of 60%, see Abstract. It would have been obvious to one of ordinary skill in the art to use calcium sulfate as taught by Barralet for the shaped particles of Black in order to provide a well accepted bone filler with a good porosity for bone ingrowth.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Kondo et al. (JP 171546). Black is explained supra. However, Black does not disclose the particle diameter in the range of 6mm. Kondo et al. teach forming particles with protruberances or extremities on the surface having a diameter of 8mm, page 3, lines 9, 10. Kondo also teaches that the particles had excellent affinity for tissue, page 2, lines 9-11. It would have been obvious to one of ordinary skill in the art to use the teaching of Kondo to use diameters "about" 6 to 8mm for the particle of Black in order to encourage greater tissue ingrowth and improve the affinity for tissue growth.

Claims 2,3, 73,74,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700 in view of Sheppard et al. (WO 94/08912). Black is explained supra. However, Black does not disclose the shaped particle having exactly six extremities. Sheppard (Fig. 2) shows the particle with six extremities, which inherently has bilateral symmetry and arms at right angles. Sheppard also teaches that a great variety of properties can be obtained by altering the interface properties in order to improve adhesiveness of the composite form, page 4, lines 1-4. Additionally, Sheppard teaches that the structure of shaped particles results in a consistent, reticulatable form, page 7, lines 7,8. It would have been obvious to one of ordinary skill in the art to use additional extremities, such as six taught by Sheppard et al. in the shaped particle of Black in order to improve the interlocking of the extremities.

Claims 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Black et al. '700. Black is explained supra. However, Black does not disclose resorbable materials for the particles. It would have been an obvious matter of design choice to have a resorbable material for the shaped particle, since applicant has not disclosed that this material for the particle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the ceramic or bioactive glass as taught by Black or the resorbable material of claim 65 because both materials are biocompatible and remain in the body of a sufficient time to permit bone ingrowth and provide the ability to fill the bone void.

Art Unit: 3738

**Response to Arguments**

Applicant's arguments with respect to claims<sup>1</sup>,<sup>26</sup> have been considered but are moot in view of the new ground(s) of rejection. <sup>and declaration</sup> <sup>SP 2/13/03</sup>

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino TC 3700, AU 3738

  
Paul Prebilic Primary Examiner

